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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43,51 and 55-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-43, 51, 55-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *1/31/2006*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 12/12/05. Claims 1-30, 44-50 and 52-54 have been canceled. Claims 31-41, 51 and 55-56 have been amended. New claims 58-63 are added. Claims 31-43, 51, 55-63 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 31-43, 51, 55-56 and 57 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,379,886B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention in current application is an obvious version of claimed invention of UDS patent No. 6,379,886B1.

3. Applicants elect to hold the issue abeyance to the time when the pending claims are in the condition for allowance. Since there is neither response nor argument to the rejection, the rejection is maintained.

New ground rejections:

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 31-43, 51, 55-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20, 21-22 of copending Application No. 11/126,662. Although the conflicting claims are not

identical, they both are directed to a diagnostic reagent with same limitations. Therefore, they are not patentably distinct from each other because they obvious each from other.

6. The claimed invention of current application is directed to a diagnostic reagent for hepatitis C virus (HCV) infection comprising a solid phase sensitized with a HCV antigens combination comprising a genetic recombinant HCV antigen with large molecular weight of more than 10,000 and one or more other antigen conjugated with a carrier protein with smaller molecular weight of less than 10,000. Whereas, the conflict claims in the co-pending application is directed to a diagnostic agent comprising a mixture of a genetic recombinant HCV antigen and one or more synthetic antigen conjugated with a carrier protein. While the later does not cite that the molecular weight for the recombinant antigens, it is obviously for the person with ordinary skill in the art to understand and accept that the synthetic antigen usually has less molecular weight since it is quit difficulty for synthesizing a protein with more than 10,000 molecular weight. However, the recombinant antigen of both applications is selected from HCV structural or non-structural protein, preferably NS3, and the conjugated antigen(s) of both applications is selected from either HCV structural and non-structural antigen of Core, NS3, BS4 and NS5. The solid phase in both applications is directed to a same material selected from group consisting of polysteren latex particle, copolymer latex particle, erythrocyte and gelatin particle. The carrier protein in the claims of both applications is also selected from same material BSA, ovalbumin and hemocyanin with same ration with same ration from 1:3 to 1:20. Therefore, they are obvious version each from other.

An obvious-type double patenting rejection is appropriate where the conflict claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (fed. Cir. 1985).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 31-43, 51, 55-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following unclearness of the claims.

9. 1). Claim 31 recites the limitation "the first antigen on line 8" in claim 31. There is insufficient antecedent basis for the limitation in the claim.

10. 2). Claim 31 is also unclear in that is fails to define which antigen is the first antigen.

11. The above rejections affect the dependent claims 32-35, 51, 55 and 58-62.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 36-43 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesneiwski et al. (WO 93/06247A1) and Lambert S. (US Patent 5,164,299A).

14. Lesneiwski et al. teach a confirmation assay comprising to use the diagnostic agent that is coated onto a polystyrene beads, wherein the agent comprises at least two polypeptides of the recombinant polypeptide C100-3 and one or more synthetic peptides of p1684, p1694, p1866 that are separately coated onto the polysteren beads. The C100-3 is directed to the HCV polyproteins from amino acid residue 1569-1930 that encodes the HCV non-structural protein NS3-NS4 with approximately molecular weight about 36,000

(More than 10,000), whereas, the synthetic HCV peptide antigen 1684 encoded amino acid residues 1684-1750 of NS4 with approximately 6700, peptide antigen 1694 encodes the NS4, and ranges from amino acid residues 1694-1735 with approximately molecular weight 4100, and peptide antigen 1866 encodes the NS45, and ranges from amino acid residues 1866-1930 with approximately molecular weight 7600. All of the synthetic antigen peptides have less than 10,000 molecular weights (See Fig. 1b and page 19). While Lesneiwski et al. do not teach to conjugate the less ten 10,000 antigen peptide with carrier protein, preferably BSA, they disclose that the synthetic antigens are further coated with BSA after they are coated onto the solid support.

15. Lambert disclose that numerous reagents and procedures comprise conjugate a protein antigen to a carrier molecule via variety functional groups between the protein and molecule, wherein the solid support can be selected wit many materials including latex particle and beads in any size (See column 3-4). He further teaches to use BSA to conjugate hepatitis B antigen and mobilized the conjugated antigen to a solid support. He concludes that the BSA conjugated antigens produce an enhanced immune response; especially the mixture of the conjugated and unconjugated antigens in a certain proportions provides an enhanced assay performance (See Abstract, columns 6-8 and claims 1-15).

16. Therefore, it would have been obvious for one with ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference by Lesneiwski et al. to make the antigen reagent with both recombinant antigen of NS3 with big molecular weight up to more than 10,000 and small synthetic antigen with less than 10,000 molecular weight and further in view of the disclosure of Lambert to conjugate the synthetic small molecular antigen peptide with BSA in order to produce an enhanced immune assay performance. Hence, the claimed invention as whole is prima facie obvious absence unexpected results.

17. Regarding to the ration of BSA and antigen peptide, applicants are reminded that the modification of the incubation time for overnight to 1:3 to 1:20 is generally recognized as being within the level of the ordinary skill in the art, In re Rose, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim

are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, In re Aller, 105, USPQ 233. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER

Bao Qun Li
02/01/2006

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2/6/06